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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/676,568

09/30/2003

Trudee Klautky

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EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/676,568	<b>Applicant(s)</b> KLAUTKY ET AL.
	<b>Examiner</b> Lyle A. Alexander	<b>Art Unit</b> 1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

In response to the 3/31/08 Appeal Brief, the Office updated the search and found new art.

In view of the Appeal Brief filed on 3/31/08, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 and 18-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-33 of copending Application No. 10/866,428. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to method of processing digital images of a biological sample and making comparisons/decisions about the sample based upon the analysis of the digital image.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 18-20,22, 24,26-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zahniser et al. (USP 5,168,066).

Zahniser et al. teach an automated method of cellular analysis. The cells are treated with a thionin stain that contrasts the cellular nuclear portion from the cytoplasm.

Column 6 lines 13-16 teach fixing the cells on the slide with an alcoholic fixing solution. This has been read on the claimed "providing a cytological sample in a solution in a vessel." The stained cell is subjected to IR and electronically imaged. The subsequent image is stored and compared to predetermined parameters to diagnosis the health of the cells. The claimed "optical interrogating" has been read on the taught electronic imaging. The claimed "attaching a positive designator to the sample ....attaching a manipulation designator" have been read on the taught steps of recording the image and comparison to certain parameters to obtain a diagnosis. Column 2 lines 24-35 teach use of stain that includes the claimed "acetic acid" and the claimed "reducing agent" (e.g. sodium or potassium hydroxide).placement of a tissue sample on a slide.

Claims 1-3, 15-16,18-20,22, 24-29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bukshpan et al. (US 2002/0198928).

Bukshpan et al. teach an automated method of sorting an identifying cells. analysis. The cells placed in a container with a solution containing photophoric probes. This has been read on the claimed "providing a cytological sample in a solution in a vessel." Paragraph [068] teaches analysis of the claimed cell types. Paragraph[0137] teaches a computer and a digital signal processor which identifies cells based upon image analysis. This has been read on the claimed identification of "mucus" and "blood." The claimed "optical interrogating" has been read on the taught imaging. The claimed "attaching a positive designator to the sample ....attaching a manipulation designator" have been read on the taught steps of recording the image and comparison to certain parameters to obtain a diagnosis.

Claims 1-16 and 18-29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Isenstein et al. (US 2004/0253144).

Isenstein et al. has an earlier effective filing date and a different inventive entity which makes it available as prior art. Figures 5-12 teach various decision trees that encompass the claimed automated method of classifying and analyzing the samples.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zahniser et al. or Bukshpan et al. in view of Zweig et al. (USP 6,629,057).

See Zahniser et al. and Bukshpan et al. Supra.

Zahniser et al. and Bukshpan et al. are silent to the claimed designator relating to the volume of sample.

Zweig et al. teach a method for verifying accurate test performance of automated analysis testing systems by routine quality control testing. Column 5 lines 7-34 teach it is desirable to detect user errors such as sufficient sample volume and abnormal reaction chemistry. The Office has read the determination of sufficient on the claimed steps of "... meets the criterion if it contains sufficient cells for performing the assay" of claim 4, the "... sample is satisfactory for automated slide preparation" of claim 6, "adequate quantity" of claim 7, "additional sample is needed for performing the assay" of claim 8 and "concentration of the cells in the sample" of claims 12-13. The Office has read the claimed "treatment of sample" of claim 9, the addition of "acetic acid" of claim 10, the addition of "reducing agent" on claim 11 on the taught steps of determining abnormal reaction chemistry (e.g. the Office notes Zahniser et al. teach both acetic acid and a reducing agent in column 2 lines 24-35 as part of the reaction chemistry ).

It would have been desirable to modify Zahniser et al. or Bukshpan et al. in view of Zweig and employ the above quality control measures to gain the advantages of having greater certainty of the validity of the results.

Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zahniser et al. or Bukshpan et al.

See Zahniser et al. and Bukshpan et al. Supra.

Zahniser et al. and Bukshpan et al. are silent to placing a "marking on the vessel" to indicate information or the status of the sample.

The basic technique of putting indicia on data which then enabled standard sorting, searching, and reporting yielded no more than the predictable outcome which

one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that "[t]he gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art."Id. at 230, 189 USPQ at 261.

It would have been within the skill of the art to modify either Zahniser et al. or Bukshpan et al. and place indicia on the sample container to enable sorting and searching as an obvious expedient.

### ***Response to Arguments***

Applicant's arguments filed 3/31/08 have been fully considered but they are not persuasive.

The Office has vacated the rejections over Licha and Rava the were made in the 11/8/07 final Office action in favor of the above rejections.

Applicants traversed the rejection over Zahniser et al. on the basis this reference fails to teach "a solution in a vessel." The Office maintains this language is sufficiently broad to have been read on the sample and various solutions on the test slide.

Applicants' state Zahniser et al. fail to teach the claimed acts of attaching a positive designator or a manipulation designator. The Office maintains the analysis taught by Zahniser et al. compares the image to a standard or known image and designates the sample image is either normal or abnormal which has been properly read on the claimed positive designator and manipulation designator.

Applicants' state Zahniser et al. fail to teach attachment of an electronic designator to the sample. The instant claim language is sufficiently broad to have been



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properly read on the analysis of the image and designation as either normal or abnormal cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander  
Primary Examiner  
Art Unit 1797

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